REMARKS:

REMARKS REGARDING DRAWING AMENDMENTS:

Responsive to the drawing objection, a Replacement Sheet showing an amended Fig. 5 is included herewith, and in which reference numeral 310 designates a first luer-lock connector and reference numeral 313 designates a second luer-lock connector. It is believed that this amendment remedies the objection.

IN RESPONSE TO THE OFFICE ACTION:

REJECTIONS UNDER 35 U.S.C. § 102:

Claims 1, 8-9, 11-12, 15-17, 20-21, 26-27, 29-30 and 33 have been rejected under 35 U.S.C. §102(b) as being anticipated by Vaillancourt (US 5897526), and separately by Hargrove *et al.* (US 4573967). In response, Applicant requests that the Examiner reconsider and withdraw the rejection in view of the following: [1]

Regarding **Vaillancourt (US 5897526),** the presently claimed invention differs from the system disclosed in Vaillancourt '526 in that a medical substance (104, 204) in fluid form is supplied from a drug container (103, 203) to a fluid container (101), such as an IV bag, containing an infusion fluid whereby the contents of the fluid container (101) are mixed with the medical substance (104, 204) inside the fluid container (101) before said mixture is administered

[1] The long-standing requirement is reminded that anticipation under §102 can only be found if a reference shows exactly what is claimed. The identical invention must be shown in as complete detail as is contained in the patent claim. Furthermore, the elements must be arranged as in the claim under review. Addressing the rejection under 35 U.S.C. §102: Examiner is reminded that for there to be anticipation under 35 U.S.C. §102, "each and every element" of the claimed invention must be found either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and references cited therein. See also *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986) ("absence from the reference of any claimed element negates anticipation."); *In re Schreiber,* 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). As pointed out by the court, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of the invention. *ATD Crop. V. Lydall, Inc.*, 159 F.3d 534, 545, 48 USPQ 2d 1321, 1328 (Fed. Cir. 1998). See also *In re Spada*, 911 F.2d 705, 708, 15 USPQ 2d 1655, 1657 (Fed. Cir. 1990).

to a patient. An inlet port of the fluid container (101) exhibits a first luer-lock connector and the drug container containing the medical substance is sealed by a cap exhibiting a second luer lock connector for attachment to the first luer lock container. A fluid barrier (101, 109, 108) is arranged to be ruptured by an external force to allow fluid passage between the drug container and the fluid container.

Furthermore, Vaillancourt '526 describes a system comprising an a fluid container (IV bag 10) and a primary line (12) communicating with said container (10) to receive and convey fluid therefrom and a second line (20) communicating with a hollow penetrating member that penetrates a membrane to access a drug vial and communicating with an arm of a Y-site connector to deliver the vial contents to the primary line. The contents of the vial do not, however, enter the container (10). Air (supplied via air vent 17 for draining the container 10) is the only fluid that enters the container via the primary line (12). This means that the medical substance from the vial is mixed with the contents of the container (10) outside the container.

Vaillancourt '526, when describing the embodiment shown in that document's Fig. 14, discloses (column 9, lines 60-63) that a clamp 22 is disposed in the primary line below a drip chamber 13 in order to prevent back flow into the bag 10, should a vial be raised above the level of the bag 10. Precautions are therefore taken to prevent a medical substance from entering the bag in contrast to the present invention which aims to introduce a medical substance into a bag.

Vaillancourt '526 also describes an embodiment (shown in Figs. 1, 6, 9 and 13) in which a reservoir bag (23) in a second line (20) is filled with fluid from the primary line (i.e. the IV-bag 10) in order to effect reconstitution or dilution of a powdered or crystalline type drug in a drug vial (25). Such an embodiment is different from the present invention in that two fluids are not mixed inside a fluid container. Instead a fluid from a reservoir bag (23) is mixed with solid matter inside a drug vial (25) (see column 8, lines 29-36).

Vaillancourt '526 further discloses an embodiment (shown in Fig. 19) in which a flexible bag 65 is provided with an injection site 73 comprising a rubber disc 75 that ensures a "seal-tight fit" (column 11, line 13) and which may be penetrated by a penetrating member 77 to inject sterile fluid from a syringe 80 into the flexible bag. The penetrating member 77 is disposed within a collapsible sleeve 78 having a septum 79. The penetrating member 77 penetrates

through the septum and the rubber disc *75.* This type of inlet port is well known and is described in the present patent application (see page 6 lines 16-19). Instead of this type of inlet port, the present invention concerns an inlet port (105, 106) that exhibits a first luer lock connector (100, 111) and a drug container whose cap exhibits a second luer lock connector. These features enable the drug container to be attached to the infusion fluid container in a very fast and safe way. The function of luer lock connectors is well known, per se, but for applications other than the fluid transfer assembly according to the invention.

Furthermore since the fluid barrier of the present invention is enclosed inside a fluid duct, it does not have to be disinfected before use as is necessary in the embodiment of Vaillancourt '526 shown in Fig. 19. It should also be noted that the embodiment of Vaillancourt '526 does not disclose a fluid barrier that is arranged to be ruptured; i.e., irreversibly torn or broken, to allow fluid passage between the bag and the syringe. The rubber disc 75 is the fluid barrier that has to be penetrated by the penetrating member 77 in order to allow fluid passage between the syringe 50 and the bag 65. The rubber disc recreates a seal-tight fit after the syringe has been withdrawn and can therefore not be said to have been ruptured.

None of the embodiments disclosed in Vaillancourt '526 disclose all of the features of claim 1 and furthermore comprise features that would lead a skilled person away from the present invention. Claim 1 is therefore novel and not anticipated by Vaillancourt '526.

In view of the above, Applicant requests the reconsideration and withdrawal of the claim rejections based on Vaillancourt '526 as being anticipation under 35 U.S.C. §102(b).

Regarding **Hargrove et al. (US 4,573,987)**, an apparatus is disclosed in which fluid passes from an IV bag (11) to a drug vial (35) containing medicine under a partial vacuum and then to a patient (12) rather than from a drug vial into an IV bag and then into a patient as in the present invention. Furthermore, Hargrove et al. '987 discloses fluid flow restricting means for releasably closing a pathway to the interior of the vial to temporarily prevent flow of fluid through said pathway (see claim 1 of Hargrove et al. '987). At column 4, lines 20-22, Hargrove et al. '987 describes a clamp 23 for regulating the flow through the tubing 19 to the drug vial. This means that a fluid flow barrier (the clamp 23) is not ruptured; i.e., irreversibly torn or

broken, since the pathway to the drug vial can be releasably closed. Present claim 1 is therefore novel with respect to Hargrove et al. '987.

In view of the above, Applicant requests the reconsideration and withdrawal of the claim rejections based on Hargrove et al. '987 as being anticipation under 35 U.S.C. §102(b).

In view of the above, Applicant requests the reconsideration and withdrawal of the claim rejections, all of which are exclusively based on anticipation under 35 U.S.C. §102(b), and asks that Examiner indicate the allowance of the claims in the next paper from the Office.

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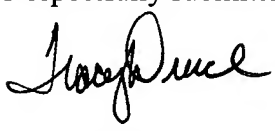
The undersigned representative requests any extension of time that may be deemed necessary to further the prosecution of this application.

The undersigned representative authorizes the Commissioner to charge any additional fees under 37 C.F.R. 1.16 or 1.17 that may be required, or credit any overpayment, to Deposit Account No. 14-1437, referencing Order No. 06730.0018.NPUS00.

In order to facilitate the resolution of any issues or questions presented by this paper, the Examiner should directly contact the undersigned by phone to further the discussion.

Respectfully submitted,



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